REMARKS

The Official Action dated January 25, 2005 has been carefully considered. Accordingly, the changes presented herewith, taken with the following remarks, are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, claim 1 has been amended to incorporate the recitation of original claim 3 and to clarify that the personal care composition is adapted to provide at least one benefit to the surface of the body to which the personal care composition is applied, as taught in the specification at, *inter alia*, page 3, paragraph 10. Claim 3 has been amended for clarification and claims 4-11 have been amended to recite dependency from claim 1. Claim 31 has also been amended to depend from claim 1. It is believed that the present amendments do not constitute introduction of new matter and that entry is therefore in order and respectfully requested.

Applicants acknowledge and appreciate the Examiner's indication of allowable subject matter. Specifically, the Examiner states that he found allowable subject matter in claim 15 because the prior art, alone or in combination, does not suggest or render obvious the peptide of SEQ ID NO: 19, a silk-elastin polymer identified as SELP 47K. The Examiner further states that the prior art teaches various SELPs, but does not teach the instant SEQ ID NO: 19. Applicants agree that personal care compositions comprising SELP 47k are patentable over the prior art.

In response to objections to the drawings by the Examiner, formal drawings have been prepared and are also being submitted in a separate paper.

Claims 1-33 are currently pending in the application.

35 U.S.C. § 112, first paragraph

Claim 1 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. While the Examiner specifically rejects claim 1, it appears to Applicants that his arguments are directed to both claim 1 and claim 3. In order to insure efficient prosecution, Applicants response is directed, therefore, to a 35 U.S.C. § 112, first paragraph rejection of amended claim 1, which incorporates the recitations of original claim 3.

The Examiner asserts that the claim contains subject matter which is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner conducts a five factor analysis, and with respect to the disclosure of the present application, asserts that: (1) the level of skill and knowledge in the art is high; (2) the claim and specification are "silent" as to "required essential components" of the repeat sequence polymer; (3) the instant claim and specification are silent as to specific physical and/or chemical properties of the repeat sequence protein polymer embraced by the claim so long as it has a repeat sequence...and is "silent to the properties of the myriad of compounds embraced by the claims;" (4) the instant claims and specification are "silent to the functional characteristics of the infinite peptides which are embraced by the instant claim," further stating that the specification only provides that SELPs, "compounds which are one species embraced by the claim," have desirable characteristics imparted from silk's durability and elastin's flexibility; and (5) the peptides are synthesized in cell culture or through synthetic routes.

Further, the Examiner asserts that instant claim 1 is a broad generic claim and that the "possible structural variation of the repeat sequence protein polymer are limitless to any class of

peptide, so long as it has some form of a repeating unit." The Examiner also asserts that "the repeat may be as simple as, though not limited to, a single amino acid being found twice within a protein sequence...[such that]...all peptides would be embraced by this claim so long as they are in a personal care composition." Hence the Examiner asserts that "there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification and that the specification lacks sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of derivatives."

The Examiner acknowledges that written description exists for "SEQ ID NO: 19, SELP-47-K, and the compounds identified in the specification tables and/or examples, but confusingly asserts that "the specification is void of any peptides, proteins, or molecules that qualify for the functional characteristics claimed as the protein polymers with functional characteristics that qualify."

For the reasons set forth in detail below, this rejection is traversed and reconsideration is respectfully requested.

First, Applicants submit that the Examiner has misread the generic formula which identifies the instant repeat sequence protein polymers (RSPP) which may be employed in the inventive compositions, and that the actual structural requirements yield a much smaller universe of RSPPs suitable for incorporation into the inventive compositions, with a much more defined structural complexity, than that assumed to exist by the Examiner. As noted above, the Examiner asserts that claim 1 encompasses composition embodiments with RSPPs having "a single amino acid being found twice within a protein sequence...[such that]...all peptides would

be embraced by this claim so long as they are in a personal care composition." Elsewhere in the Office Action the Examiner asserts that the structural formula of the RSPP reduces merely to B_2.

In his analysis based on this misconstruction, the Examiner clearly under-appreciates the complexity and uniqueness of the RSPP ingredient, overstates the number of possible compounds encompassed by the structural formulation limitation, and under-appreciates the representative nature of the species disclosed by the Applicants. Applicants submit that the Examiner's conclusion of insufficiency of written description is based in large part on his failure to appreciate the scope of this formula and the resulting failure to comprehend the surprising discovery by the present inventors that RSPP's of this unique configuration retain the known functional characteristics of their component repeat sequence proteins, and may confer aspects of those characteristics to a treated body surface or membrane when combined and incorporated into personal care compositions and applied to the body surface or membrane. Hence, an understanding of the true breadth of this structural formula limitation is important to overcoming the written description rejection.

Applicants therefore draw attention to the RSPP formula recited in amended claim 1. Applicants respectfully submit that the Examiner's interpretation that all of the sub-enumeratives y, y', y", x, x', and x" can be 0 in a single embodiment is incorrect. While it is true that the y and x categories are each modified by being defined by ranges that include 0, the Examiner overlooked the relevant "wherein clause" that also limits and defines x. The entire clause directed to defining the x category of enumeratives is as follows: "x, x' and x" are each 0 or an integer of at least 1, *wherein each integer varies to provide for at least 30 amino acids in the A, A' and A" individual repeating sequence units,* and wherein the integer of x and the integer of x" are the same as or different from the integer of x." Semicolons at the beginning and end of this

clause set it off as integral. Prior in the formula, A, A' and A" are defined as individual repeating sequence units comprising "from 3 to about 30 amino acids," while n, n' and n" are the sub-enumeratives of A, A' and A" respectively, and are integers of at least 2 and not more than 250. Hence, up to the point of categorically defining A_n , a minimum peptide of 6 amino acids results. At this point, x, x' and x" are defined as the sub-enumeratives of (A_n), $(A'_{n'})$ and $(A"_{n"})$, respectively. It is true that if all x's are 0, in the absence of any other qualifications, this value would reduce to 0 itself. However, the additional recitation that the integers selected for x must vary to provide for at least 30 amino acids in the A, A' and A" individual repeating sequence units prevents this from happening. Applicants submit therefore that *by deductive implication* it is logically incontrovertible that at least one of x, x' or x" cannot be 0 in order for there to be at least 30 amino acids in the A, A' and A" individual repeating units. Indeed, it is clear from reading the entire clause that the minimum peptide length described by this structural formula is 30 amino acids, which is the result if y, y', b and b' are all 0, and x, x' and x" are varied to yield the requisite 30 minimum. Hence, in contraindication to the Examiner's analysis, Applicants submit that the present specification does provide disclosure and written description of specific structural requirements defining the essential components employed in the present inventive compositions.

Moreover, pages 4 and 5 of the instant specification disclose many naturally occurring representative proteins which comprise base repeating sequence units and which are suitable to form the RSPP's defined by instant claim 1. The compounds encompassed by instant claim one are far more circumscribed than the "nearly every peptide with a repeating unit" asserted by the Examiner. Applicants submit that the disclosure of representative species in the specification constitutes a level of written description sufficient to support the breadth of instant claim. While

the present illustrative examples employ predominantly the SELP 47K RSPP, this is due to the focus of the examples being to provide specific personal care composition embodiments. In fact, example 15 discloses 37 exemplary personal care composition embodiments wherein any suitable RSPP may be employed.

The processes for manufacturing any particularly desirable RSPP from the disclosed proteins are known in the art and characteristics of the proteins themselves are known in the art. One of ordinary skill in the formulation arts, upon reading the present specification, would immediately recognize selection criteria with respect to the RSPP protein components according to specifically desired characteristics. The specification clearly teaches that selection of the proteins which form the RSPP is based on what characteristics are desired in a particular personal care composition embodiment.

According to case law governing the application of the written description requirement, a sufficient description of a genus may be achieved in several ways. One of them is by disclosure of a "representative number" of species as noted by the Examiner. But another is "by recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Applicants respectfully point out that this requirement is notably not a conjunctive, but an either/or. *Regents of the University of California v. Eli Lilly & Company*, 119 F.3d 1559, 1569, 43 U.S.P.Q. 2d 1398, 1406 (Fed. Cir. 1997). This case law is cited approvingly in the USPTO's "Revised Interim Written Description Guidelines," Example 7.

For these reasons, Applicants submit that the language of amended claim 1 is fully described by the present specification in accordance with the requirements of 35 U.S.C. § 112, first paragraph, whereby the rejection has been overcome. Reconsideration is respectfully requested.

35 U.S.C. § 102

Claims 1 and 3 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,614,194 to Coleman et al. Specifically, the Examiner asserts that the generic structural formula used to define the RSPPs suitable for inclusion in the inventive compositions of amended claim 1 reduces minimally merely to B_2. The Examiner further asserts that Coleman discloses the sequence "QAQGDGADAGQP," repeated at least twice, in a physiologically acceptable carrier. The Examiner notes that the Coleman composition "is a vaccine," and insists that "a vaccine is a personal care composition." This rejection is traversed and reconsideration is respectfully requested.

Amended claim 1 is directed to a personal care composition comprising an effective amount of a repeat sequence protein polymer and a physiologically acceptable carrier or excipient. The repeat sequence protein polymer comprises a specified structural formula (see claim 1, above), and the personal care composition is adapted to provide at least one benefit to the surface to which the personal care composition is applied.

Coleman, on the other hand, relates to the field of antigens suitable for providing immunity against malaria when incorporated into a vaccine (column 1, lines 20-22). The proteins employed by Coleman function antigenically, that is, to stimulate the production of antibodies specifically immunoreactive to the protein when the protein is administered to a test animal under conditions known to elicit antibody production (column 3, lines 4-9). The only composition disclosed by Coleman as comprising the active peptide is a vaccine for immunizing a susceptible mammal against malaria (see, e.g. column 22, lines 43-44). The only route of administration of the compositions taught by Coleman is via "immunization" described solely through references to injection procedures (column 9, lines 16-21).

Applicants respectfully submit that, contrary to the assertion of the Examiner, a vaccine is not understood to be a personal care composition either within the personal care formulation arts, or, most importantly, according to the definition of the phrase "personal care composition" as set forth by the Applicants in the present specification. Applicants explicitly define "personal care composition" as referring to "a product for application to the skin, hair, nails, oral cavity and related membranes for the purpose of improving, cleaning, beautifying, therapeutically treating, and caring for these surfaces and membranes" (page 4, paragraph 15).

The Coleman compositions are not applied to a surface or membrane, but are injected directly into the subderma body mass. Throughout the present specification and in all examples, the present personal care products, including the therapeutic personal care products, are applied directly to the surface or membrane to be treated.

Further, the Coleman vaccine composition does not fall under any of the functional categories used to presently define "personal care composition." With respect to embodiments involving possible medicinal applications, the present definition only mentions a therapeutic function. The therapeutic embodiments disclosed in the instant specification include, *inter alia*, acne treatments, anti-fungals, hemorrhoidal ointments, and the like. The function of the Coleman vaccine compositions, on the other hand, is prophylactic and preventative, not therapeutic. There is nothing in the Coleman disclosure teaching or suggesting that the vaccine composition may be used to ameliorate, heal or otherwise therapeutically treat subjects who have already contracted malaria.

Hence, Applicants submit that it is clear from this comparison of the Coleman vaccine to the amended claim 1 that a "vaccine composition" does not constitute a "personal care composition" as contemplated by the present invention.

Further, an ordinary person skilled in the formulation arts would not consider a vaccine composition to be a personal care composition. Using the keyword search protocol for the USPTO full text database available on-line at www.uspto.gov, Applicants conducted a search using the terms "personal care composition" and inject$," and failed to find a single patent disclosing a personal care composition which is intended to be administered by injection. A similar search within the same database conducted with merely the phrase "personal care composition," yielded 167 results. Inspection of these issued patents failed to yield a single definition of "personal care composition" which included a reference to vaccines. Applicants admit that while it is theoretically conceivable that a particular peptide may function as an effective active agent in personal care compositions and may also possess useful antigenic properties if formulated into a vaccine composition, the compositions themselves, when adapted via means well-known to formulation chemists to their respective intended uses, are simply not interchangeable. Coleman and the present specification provide a good illustration of that, as a review of the examples reveals a complete lack of overlap between the carriers, buffers, reagents and other ingredients. Indeed, the "carrier" ingredient of instant claim 1 is taught in the present specification to be "suitable for topical application to the skin or hair" (page 13, paragraph 42) and of "a sufficient thickness or yield point to prevent particles from sedimenting" (page 14, paragraph 45). Clearly, the carriers and vehicles disclosed by Coleman as suitable for compositions intended to be injected are unsuitable for topical application. And, significantly, Coleman provides exceptional guidance to formulating vaccine compositions, but absolutely none to formulating personal care compositions.

Anticipation under 35 U.S.C. § 102(b) requires the disclosure in a single prior art reference of each element of the claims under consideration, *Alco Standard Corp. v. TVA*, 1 U.S.P.Q.2d 1337, 1341 (Fed. Cir. 1986). The corollary of the rule is that absence from the reference of any claimed element negates anticipation. *Kloster Speedsteel AB v. Crucible Inc.,* 793 F.2d 1565, 230 USPQ 81 (Fed.Cir. 1986). Coleman fails to teach or suggest a *personal care composition* comprising an effective amount of a repeat sequence protein polymer and a physiologically acceptable carrier or excipient wherein the repeat sequence protein polymer comprises a repeating sequence of at least three amino acids and further *wherein the personal care composition is adapted to provide at least one benefit to the surface to which the personal care composition is applied.*

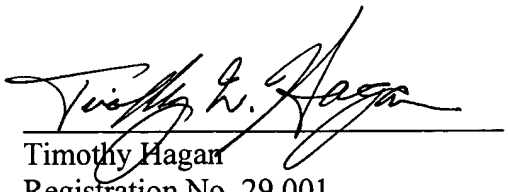
For these reasons, Applicants submit that Coleman does not anticipate present independent claim1, or present claim 3 dependent therefrom. Hence, the rejection of instant claims 1 and 3 under 35 U.S.C. § 102 over Coleman is overcome and reconsideration is respectfully requested.

Proper Rejoinder

In a section of the January 25th Office Action designated "Examiner Elected Species" (page 3) the Examiner notes that he extended a search to a peptide sequence disclosed by Coleman and subsequently withdrew claims 4-9, 12-14 and 31 from further consideration. In addition, the Examiner withdrew claims 10 and 11 as not reading on the elected species, there being no other allowable linking claim. In view of the previous remarks and arguments which demonstrate the patentability of independent claim 1 over Coleman, and there thus being an allowable generic or linking claim, Applicants respectfully ask for reconsideration, rejoinder, and examination of claims 4-9, 10-11, 12-14, and 31.

It is believed that the above represents a complete response to the rejections under 35 U.S.C. §§ 102 and 112, first paragraphs, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,



Timothy Hagan
Registration No. 29,001

One Dayton Centre
One South Main Street, Suite 1300
Dayton, Ohio 45402-2023
Telephone: (937) 223-2050
Facsimile: (937) 223-0724

TWH/DME/amm